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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,219	11/07/2001	Walter E. Dewolf	GM50056	5535

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,219	DEWOLF, WALTER E.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

[1] Claims 1-17 are pending in the application.

[2] Receipt of an information disclosure statement filed October 30, 2003, is acknowledged.

Lack of Unity

[3] Applicant's election with traverse of Group I, claims 1-10 and the species of Group a, uncompetitive inhibition by Apo-ACP versus NADH, filed September 29, 2003, is acknowledged. Applicant traverses the restriction by arguing that examination of the non-elected claims of Groups II-IV would entail a search of Group I and that co-examination of all pending claims would place no undue burden on the examiner. Applicant's argument is not found persuasive.

The examiner maintains his position that the claims of Group I and the claims of Groups II-IV do not have unity of invention and co-examination of the claims of Groups II-IV with the claims of Group I would place a serious burden on the examiner. First, it is noted that applicant does not dispute that the inventions of Groups I-IV do not share a special technical feature for those reasons set forth in item 6 of the Office action mailed July 25, 2003, and therefore, do not have unity of invention. To the extent the lack of unity is made under 35 USC 121, it is noted that a search for each of the inventions requires independent considerations which would require the examiner to focus on different features and recited limitations and thus would entail differently structured word

searches for both patent and non-patent literature for each of the additional groups. For example, Therefore, co-examination of the claims of Groups II-IV with the elected Group I would place a serious burden on the examiner.

[4] The requirement is still deemed proper and is therefore made FINAL.

[5] Claims 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

[6] Claims 1-10 are being examined only to the extent the claims read on the elected invention of Group I.

Drawings

[7] The drawings are objected to as the drawings include Figure 8 and Figure 8A. It is suggested that applicant renumber Figure 8A as Figure 18 and amend the Brief Description of Drawings section accordingly.

Specification/Informalities

[8] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Fabl Antagonist"

[9] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (page 64, line 14) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms

of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

[10] The specification remains objected to for those reasons set forth in item 4 of the Office action mailed July 25, 2003. Applicant failed to respond to this objection in the response to the aforementioned Office action.

[11] The specification is objected to as there is no description of Figure 8A.

Claim Objections

[12] Claims 1-8 and 10 are objected to as the claims recite non-elected subject matter, *i.e.,* the subject matter of Group II. It is suggested that applicant amend the claims so that they no longer recite non-elected subject matter.

[13] Claims 1-3, 5-6, 8, and 10 are objected to because of the following informalities: the terms "activity a polypeptide" in claim 1 and "a antibacterially" in claims 2-3, 5-6, 8, and 10 are grammatically incorrect and should be replaced with, for example, "activity of a polypeptide" and "an antibacterially". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[14] Claim(s) 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 1-10 are confusing in the recitation of "activity [of] a polypeptide... ...wherein said activity is... ...uncompetitive inhibition by Apo-ACP versus NADH". Neither the specification nor the prior art describes Fab I as having an activity of uncompetitive inhibition. Furthermore, it is unclear as to the activity that is inhibited by the claimed or recited antagonist. Based on the disclosure, it would appear the claims are to be interpreted as being drawn to an antagonist that inhibits an FabI enoyl-ACP reductase activity (see page 3, line 30 to page 4, line 4 of the specification) and methods of treatment using said antagonist. However, as written, the claims are drawn to an antagonist that inhibits uncompetitive inhibition by Apo-ACP versus NADH or methods of treatment using said antagonist. Such an antagonist would therefore inhibit uncompetitive inhibition of Fab I. It is suggested that applicant clarify the meaning of the claims.

[b] Claims 2, 5, and 10 are unclear in the recitation of "an individual having need to inhibit... ...Fab I polypeptide" as neither the specification nor the prior art provide any indication as to how one distinguishes an individual in need of inhibiting Fab I from any other individuals. It is suggested that applicant clarify the meaning of the claims.

[c] Claims 1-2, 3 (claim 4 dependent therefrom), 5, 6 (claim 7 dependent therefrom), and 8-10 are unclear in the recitation of "NADH (Ki(app)". The term

"$K_{i(app)}$" is recognized in the art as meaning an apparent inhibitory constant. However, in the context of the claims, it is unclear as to why this term has been recited in the claims. It is suggested that applicant clarify the meaning of the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[15] Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-10 are drawn to an antagonist that inhibits uncompetitive inhibition of the FabI by Apo-ACP versus NADH and methods of treatment using said antagonist.

The claimed antagonist and method of treatment have no substantial utility as further experimentation is required to establish their "real world" use as explained in detail below. The utility of the antagonist will be addressed first followed by the utility of the method of treatment.

Regarding the claimed antagonist, it is noted that the specification fails to disclose even a single antagonist that inhibits uncompetitive inhibition of Apo-ACP versus NADH. While antagonists of FabI enzymatic activity are known in the art (see, *e.g.,* Heath et al. *J Biol Chem* 275:4654-4659), there is no evidence in the prior art or

the instant specification that any of these inhibitors has the ability to inhibit uncompetitive inhibition of Apo-ACP versus NADH. Thus, as such evidence has not been disclosed, further experimentation would be required to isolate such inhibitors or examine existing inhibitors for such activity.

As further experimentation is clearly required to isolate the claimed antagonist or examine existing antagonists for such activity, it follows that further experimentation is necessary for the claimed methods of treatment that use such an antagonist. Furthermore, even assuming *arguendo* that such an antagonist were disclosed in the specification and/or the prior art, the specification fails to provide the necessary guidance for using such an antagonist to successfully treat an individual. Thus, even if an antagonist having the ability to inhibit uncompetitive inhibition of Apo-ACP versus NADH were disclosed in the specification and/or prior art, further experimentation would be required for one of ordinary skill in the art to practice the claimed methods.

Further experimentation is clearly required to isolate and/or establish a "real world" use for the claimed antagonist and further experimentation is clearly required for using the claimed antagonist to treat an individual. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson,* 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966), "[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Here the

specification fails to provide a specific benefit in currently available form for the claimed antagonist and method of use thereof for treatment of an individual. For the reasons stated above, the claimed antagonist and method of use thereof have no specific and substantial utility.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[16] Claim(s) 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim(s) 1-4 and 9-10 are drawn to a genus of antagonists that inhibit an activity of a polypeptide comprising an amino acid sequence at least 90% identical to SEQ ID NO:2 or 4 including SEQ ID NO:2 or 4, wherein the activity is uncompetitive inhibition by Apo-ACP versus NADH and methods of treating an individual using said antagonist. Claims 5-8 are drawn to a method for treatment using an antagonist that inhibits the activity of any FabI polypeptide, wherein the activity is uncompetitive inhibition by Apo-ACP versus NADH.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a

representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose even a single representative species of the genus of claimed antagonists that inhibit uncompetitive inhibition by Apo-ACP versus NADH. In the absence of a single representative species of the claimed or recited genus of antagonists, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[17] Claim(s) 1-10 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

[18] Status of the claims:

- Claims 1-17 are pending.
- Claims 11-17 are withdrawn from consideration.
- Claims 1-10 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

12-22-03
DAVID STEADMAN
PATENT EXAMINER